Protocol Information Office
Division of Cancer Prevention, NCI,NIH,DHHS
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DCP Consortia Protocol Submission Worksheet

Please print or type. Complete all relevant sections. Attach this form to all protocol submissions and submit to the above address.

Section 1: Overview of Protocol Information

Consortium Name:
Consortium Principal Investigator:
DCP Protocol #: Local Protocol #:
Protocol Title:
Protocol Chair Organization:
Protocol Chair:
Is this a Multi-Institutional Protocol? ☐yes ☐no
? If yes, list the name of each Protocol Lead Investigator and Organization:
Will CCOPs be participating in this protocol? ☐yes ☐no
? If yes, indicate name of individual CCOPs or CCOP Research Base:
Will additional funding be used from other NIH funding mechanism(s)? ☐ yes ☐ no ☐ pending
? If yes, provide the Grant No. or CA No: (*NCI: U01-CA-12345)*
Are you receivi ng support from non-NCI sources (i.e., industry, ACS) for this study? ☐ yes ☐ no ☐ pending
? If yes, specify the source and use of funds:
Will this study be conducted under an IND? ☐ yes ☐ no ☐ unknown
IND Sponsor: ☐ DCP ☐ Investigator (name): ☐ Pharmaceutical Company (name):
IND Number (if known):

Section 2: Purpose of Protocol Submission

☐ First Submission to DCP PIO	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
☐ Revised Protocol *(changes made to the protocol prior to NCI approval)*	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
☐ Amended Protocol *(changes made to protocol after NCI approval)*	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
☐ Other, specify:	Document date:	Version Number:	IRB Submission Date (if applicable):	PIO Submission Date:
Is this document submitted in response to a DCP review? ☐ yes ☐ no				
▪ If yes, date of DCP review letter:				

Section 3: Overview of Protocol Design

Study Phase: ☐ I ☐ I/II ☐ II ☐ Other, specify:			
Study Population (describe):			
Study Endpoints (select ALL that apply)			
☐ Single dose Pharmacokinetics	☐ Dose Selection for Phase II	☐ Safety	☐ Intermediate Biomarkers
☐ Multi dose Pharmacokinetics	☐ Drug Effect Measurements	☐ Efficacy	☐ Feasibility
☐ Other, specify:			

Study Participant Accrual Details		
Projected Study Start Date:	Total Sample Size:	Projected Accrual Rate:
Projected Completion Date of Accrual:	Estimated # evaluable:	Estimated # withdrawals:
Expected # subjects/site:	# Case Report Forms per subject:	

SECTION 4: Required Gender and Minority Accrual Estimates

In accordance with the NIH guidelines on the inclusion of women and minorities as subjects in clinical research, the Department of Health and Human Services (HHS) requires that all Phase 2 and 3 trials must include accrual targets for males, females and minorities. The accrual targets should reflect the expected accrual over the life of the study.

The policy states that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The NCI suggests that the accrual targets be based on data from similar trials completed by your organization during the previous five years. It is hoped that the accrual targets will resemble the gender, ethnic and racial composition of the U.S. population as closely as possible

Ethnic Categories:	**Hispanic or Latino –** a person of Cuban, Mexican, Puerto Rico, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino." **Not Hispanic or Latino**
Racial Categories:	**American Indian or Alaskan Native –** a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment. **Asian –** a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.) **Black or African American –** a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." **Native Hawaiian or other Pacific Islander –** a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. **White –** a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

EXAMPLE
Accrual Targets

Ethnic Category	Sex/Gender				
	Females		Males		Total
Hispanic or Latino	20	+	10	=	30
Not Hispanic or Latino	40	+	30	=	70
Ethnic Category: Total of all	60 (A1)	+	40 (B1)	=	100 (C1)
Racial Category					
American Indian or Alaskan Native	1	+	0	=	1
Asian	1	+	1	=	2
Black or African American	1	+	0	=	1
Native Hawaiian or other Pacific	7	+	9	=	16
White	50	+	30	=	80
Racial Category: Total of all	60 (A2)	+	40 (B2)	=	100 (C2)
	(A1 = A2)		(B1 = B2)		(C1 = C2)

Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable).The totals provided for each Ethnic/gender or Ethnic/total combination must match those given for each Race/gender or Race/total combination (i.e., A1 must match A2, B1 must match B2, and C1 must match C2).

Accrual Targets

Ethnic Category	Sex/Gender				
	Females		Males		Total
Hispanic or Latino		+		=	
Not Hispanic or Latino		+		=	
Ethnic Category: Total of all subjects	(A1)	+	(B1)	=	(C1)
Racial Category					
American Indian or Alaskan Native		+		=	
Asian		+		=	
Black or African American		+		=	
Native Hawaiian or other Pacific Islander		+		=	
White		+		=	
Racial Category: Total of all subjects	(A2)	+	(B2)	=	(C2)
	(A1 = A2)		(B1 = B2)		(C1 = C2)

Section 5: Study Agent(s)

Agent Name	Request for DCP-Supplied	Dose & Schedule	CAS Registry No. (if known)
	☐yes ☐no		
	☐yes ☐no		
	☐yes ☐no		

Section 6: Study Related Documents Checklist

Please indicate the documents submitted for DCP review and approval, and note reason for submission. Check all that apply.

☐ Protocol: ☐ First submission ☐ Revision ☐ Amendment

☐ Informed Consent: ☐ First submission ☐ Revision ☐ Amendment

☐ Protocol Budget: ☐ First submission ☐ Revision

☐ Recruitment and Retention Plan: ☐ First submission ☐ Revision

☐ Pharmacokinetic and Biomarker Methods Development Report: ☐ First submission ☐ Revision

☐ Case Report Form (CRF) Package: ☐ First submission ☐ Revision

- ☐ Attachment #1: Schedule of Forms ☐ First submission ☐ Revision
- ☐ Attachment #2: Case Report Forms ☐ First submission ☐ Revision
- ☐ Attachment #3: Coding Conventions ☐ First submission ☐ Revision
- ☐ Attachment #4: Data Management Staff Lists
  - ☐ Section 1: Key Staff and Qualifications ☐ First submission ☐ Revision
  - ☐ Section 2: All Staff and Assigned Roles ☐ First submission ☐ Revision

☐ Data and Safety Monitoring Plan (DSMP)

- ☐ Standard approved plan on file DCP DSMP approval date:
- ☐ Attachment #1: Master DSMP Addendum

☐ Multi-Institutional Monitoring Plan (MIMP)

- ☐ Standard approved plan on file DCP MIMP approval date:
- ☐ Attachment #1: Master MIMP Addendum

☐ Data Management Plan (DMP)

- ☐ Standard approved plan on file DCP DMP approval date:
- ☐ Attachment #1: Master DMP Addendum

☐ Other *(specify)*:

Section 7: Person Completing Worksheet

Name (*please print*): _____

Phone Number: _____

E-mail Address: _____

Date Completed: _____